

REMARKS

Claims 1 and 61-115 were pending in this application.

Claims 71-73, 91-93, and 104-106 were previously withdrawn from consideration.

Claims 1, 61-70, 74-90, 94-103, and 107-115 have been rejected.

Claims 1, 61, 65, 66, 68, 70, 72-74, 77-82, 85-88, 90, 92-97, 99-101, 103, 105, 106, and 108-115 have been amended as shown above.

Claims 62 and 67 have been cancelled.

Claims 116 and 117 have been added.

Claims 1, 61, 63-66, and 68-117 are now pending in this application.

Reconsideration and full allowance of all pending claims are respectfully requested.

I. RESPONSE TO NOTICE OF NON-COMPLIANT AMENDMENT

In response to the Notice of Non-Compliant Amendment dated July 21, 2009, the Applicant respectfully notes the following.

First, Claims 103 and 104 have been corrected as shown above. These claims depend from Claim 80, rather than from Claim 86.

Second, Claims 1, 61, 63-66, 68-70, 74, 75, 77-90, 94-99, 101-103, 109, 110, and 112-115 are readable on the species elected in response to the restriction requirement dated March 15, 2004.

Third, the Applicant is not required to specifically point out how each claim amendment is supported in the originally-filed specification. MPEP § 714.02 and MPEP § 2163.06 merely

state that an applicant “should” point out support in the specification for amendments to the claims. However, neither MPEP section requires the Applicant to do so. It is therefore improper for the Office to refuse entry of the Applicant’s prior response on the basis that the Applicant failed to do something that the MPEP does not require (and is therefore optional).

However, to advance the prosecution of this matter, the Applicant provides the following information:

- The use of a prosthesis with a “non-circular” body is supported in Figures 6-27, which illustrate straight or curved prostheses that do not form complete circles or rings (and are thus non-circular).
- The use of “at least one” material listed in Claims 70, 72, and 73 is supported at page 25, line 11 through page 27, line 1 of the specification. Note, for example, the specification states that a prosthesis exterior could be formed from “any” of the listed materials. Also note that the materials in Claim 70 could overlap, such as when a synthetic resin is flexible. Further, since the disclosure supports the use of materials such as fluids and gels, Claim 72 properly recites that an internal cavity can be filled with at least one of a fluid and a gel. Similarly, the disclosure supports the use of materials such as water, saline solutions, oils, silicones, collagens, and gelatins. As a result, Claim 73 properly recites that an internal cavity can be filled with at least one of water, a saline solution, an oil, silicone, collagen, and gelatin.
- The use of an “inner” major surface in Claim 94 is supported by page 16, lines 7-17 of the specification, which states that the ridge 214 in Figure 2 is provided on the inner surface 212 of the prosthesis 200.

- Claim 100 depends from Claim 87, which depends from Claim 86. Claim 86 recites a prosthesis body with a planform having a longer first dimension and a smaller second dimension. Claim 87 recites that a second surface is planar, and Claim 100 recites that the second surface is curved along the first dimension. Figure 10 clearly illustrates a prosthesis 300 having a planar surface 316, and Figure 9 clearly illustrates the planar surface 316 is curved along the longer dimension (the length) of the prosthesis 300. The same support exists for Claims 116 and 117.

To avoid any issues with other amendments to the claims, the Applicant also notes that the ends of the prostheses in this application are “free” ends in that they are not coupled to any other prostheses or other structures. Various dimensions are shown in the figures as being “longer” and “shorter.” Various amendments were also made to resolve possible antecedent basis issues (which require no explanation) and to remove elements objected to in the Office Action.

Accordingly, all amendments to the claims are proper and should be entered.

II. REJECTION UNDER 35 U.S.C. § 112

The Office Action rejects Claim 1 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The Applicant has amended Claim 1 as shown above. Among other things, these amendments remove the claim elements forming the basis of the § 112 rejection.

Accordingly, the Applicant respectfully requests withdrawal of the § 112 rejection.

III. REJECTIONS UNDER 35 U.S.C. § 102 AND § 103

The Office Action rejects Claims 61, 63-66, 68-70, 80-88, 90, 94-101, 103, and 108-115 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,354,331 to Schachar (“*Schachar*”). The Office Action rejects Claims 61-70, 74-79, 89, 102, and 107 under 35 U.S.C. § 103(a) as being unpatentable over *Schachar*. These rejections are respectfully traversed.

A prior art reference anticipates a claimed invention under 35 U.S.C. § 102 only if every element of the claimed invention is identically shown in that single reference, arranged as they are in the claims. (*MPEP* § 2131; *In re Bond*, 910 F.2d 831, 832, 15 U.S.P.Q.2d 1566, 1567 (Fed. Cir. 1990)). Anticipation is only shown where each and every limitation of the claimed invention is found in a single prior art reference. (*MPEP* § 2131; *In re Donohue*, 766 F.2d 531, 534, 226 U.S.P.Q. 619, 621 (Fed. Cir. 1985)).

In *ex parte* examination of patent applications, the Patent Office bears the burden of establishing a *prima facie* case of obviousness. (*MPEP* § 2142; *In re Fritch*, 972 F.2d 1260, 1262, 23 U.S.P.Q.2d 1780, 1783 (Fed. Cir. 1992)). The initial burden of establishing a *prima facie* basis to deny patentability to a claimed invention is always upon the Patent Office. (*MPEP* § 2142; *In re Oetiker*, 977 F.2d 1443, 1445, 24 U.S.P.Q.2d 1443, 1444 (Fed. Cir. 1992); *In re Piasecki*, 745 F.2d 1468, 1472, 223 U.S.P.Q. 785, 788 (Fed. Cir. 1984)). Only when a *prima facie* case of obviousness is established does the burden shift to the Applicant to produce evidence of nonobviousness. (*MPEP* § 2142; *In re Oetiker*, 977 F.2d 1443, 1445, 24 U.S.P.Q.2d 1443, 1444 (Fed. Cir. 1992); *In re Rijckaert*, 9 F.3d 1531, 1532, 28 U.S.P.Q.2d 1955, 1956 (Fed. Cir. 1993)). If the Patent Office does not produce a *prima facie* case of unpatentability, then

without more the Applicant is entitled to grant of a patent. (*In re Oetiker*, 977 F.2d 1443, 1445, 24 U.S.P.Q.2d 1443, 1444 (Fed. Cir. 1992); *In re Grabiak*, 769 F.2d 729, 733, 226 U.S.P.Q. 870, 873 (Fed. Cir. 1985)).

Regarding the discussion in *Schachar* of a “scleral alloplant,” all portions of *Schachar* mentioning the alloplant are reproduced below:

The diameter of the sclera overlying the ciliary body can also be increased by making a complete periglobular incision and grafting into the incision appropriate tissue and/or physiologically acceptable structural material to increase the dimensions of the sclera. Thus an artificial scleral alloplant made of purified human collagen may be engrafted into such an incision. Other known biocompatible materials, e.g., poly(ethylene terephthalate), that are conventionally used in the construction of prosthetic devices may also be used for engrafting into such an incision. It is also possible to excise a small strip of sclera from the region overlying the ciliary body and replace it with a scleral alloplant as described above to provide an appropriate increase in the diameter of this region. (*Col. 8, Lines 12-26*) (underlining added).

This portion of *Schachar* first refers to implanting a scleral alloplant into a “complete periglobular incision.” The use of the prefix “peri” in the term “periglobular” indicates that the incision is formed completely “around” the globe, based on the standard definition of “peri” (another definition of “peri” is “near,” which cannot be the correct definition here since an incision “near” the globe of the eye would not actually be formed in the eye). As a result, this portion of *Schachar* specifically teaches forming an incision around the entire globe of the eye.

Once that incision is formed, an alloplant is engrafted into the complete periglobular incision. Nothing in *Schachar* describes any structure of the alloplant. At most, *Schachar* might teach or suggest that the alloplant is in the shape of a complete circle or ring (as is the scleral

band disclosed in *Schachar*).

This portion of *Schachar* then refers to excising a small strip of sclera from the eye and replacing the strip with the same “scleral alloplant as described above.” In other words, this part of *Schachar* refers to the same alloplant, not a second or different alloplant. Again, at most, *Schachar* might teach or suggest that the alloplant is in the shape of a complete circle or ring, and nothing in *Schachar* describes any structure of the alloplant.

In contrast, the independent claims have been amended to refer to specific surface shapes. For example, Claim 1 recites a prosthesis with two “free ends,” one surface that is “planar,” and an opposing surface that includes “a ridge or a crest separated from the planar surface.” Since *Schachar* provides absolutely no description of any structure of the alloplant, none of these features are taught or suggested by *Schachar*.

Similarly, Claims 61, 74, and 109 refer to a prosthesis with two “free ends,” a “planar” surface, and “a ridge or a crest” on a different surface. Claim 80 refers to a body having two “free ends” and a “ridge projecting above surrounding portions of the body,” where the ridge is located between “first and second edges of the body” and extends along “at least a majority of a length of the body from the first free end to the second free end.” Claim 94 refers to a “base member” having an elongated planform with an “inner major surface” and a “planar outer major surface,” where a “ridge member” is on the inner major surface. Claim 108 refers to an “arcuate base” that is “planar” and that has a “length that forms less than a complete circle,” where there is a “ridge on a surface of the base.” Again, since *Schachar* provides absolutely no description of any structure of the alloplant, none of these features are taught or suggested by *Schachar*.

Regarding the assertion that the scleral band of *Schachar* can anticipate the claims, every single independent claim includes language that cannot be taught or suggested by the scleral band of *Schachar*. Claims 1, 80, and 109 recite that a body is “non-circular” and has two “free ends.” This structure cannot be taught or suggested by the complete circular band of *Schachar*.

Claim 61 recites that an elongated body has multiple “free ends,” where a first free end is “more distal” from a second free end “than from any other portion of the elongated body.” Claim 74 recites that a body has multiple “free ends” that are “adapted to be free of contact with any other prosthesis when the prosthesis is implanted,” where the body has “no portions that are spaced apart from each other further than the first and second free ends.” Neither of these structures are taught or suggested by the complete circular band of *Schachar*.

Claim 94 recites a “non-circular” body, and Claim 108 recites an “arcuate base” that has a “length forming less than a complete circle.” Once again, this cannot be taught or suggested by the complete circular band of *Schachar*.

For these reasons, *Schachar* fails to anticipate or suggest the Applicant’s invention as recited in all pending independent claims (and their dependent claims). Accordingly, the Applicant respectfully requests withdrawal of the § 102 and § 103 rejections and full allowance of all pending claims.

CONCLUSION

The Applicant respectfully asserts that all pending claims in this application are in condition for allowance and respectfully requests full allowance of the claims.

If any issues arise or if the Examiner has any suggestions for expediting allowance of this application, the Applicant respectfully invites the Examiner to contact the undersigned at the telephone number indicated below or at *wmunck@munckcarter.com*.

The Director is hereby authorized to charge any fees connected with this communication or credit any overpayment to Deposit Account No. 50-0208.

Respectfully submitted,

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